

## **NEWS RELEASE**

# Coya Therapeutics to Present ALS Clinical Study Data for its Investigational Biologic Combination at the 2023 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference.

#### 2/27/2023

- Dr. Stanley Appel to present data from a proof-of-concept open-label clinical study in patients with ALS.
- ALS patients were treated with Coya's investigational biologic combination (COYA 302) administered subcutaneously over a 12-month period.
- The study evaluated safety and tolerability, regulatory T cell (Treg) function, serum blood biomarkers, and clinical status and function (ALSFRS-R scale).

HOUSTON--(BUSINESS WIRE)-- Coya Therapeutics, Inc. (NASDAQ: COYA) ("Coya" or the "Company"), a clinical-stage biotechnology company developing multiple therapeutic platforms intended to enhance Treg function, including biologics and cell therapies, today announced the presentation of results from an academic clinical study in patients with Amyotrophic Lateral Sclerosis (ALS) with Coya's proprietary investigational biologic combination at the 2023 MDA Clinical & Scientific Conference in Dallas, Texas, to be held in-person and virtually from March 19 to March 22, 2023.

The proof-of-concept open-label clinical study is the first-of-its-kind evaluating a dual-mechanism immunotherapy for the treatment of ALS. Patients in the study received investigational treatment for 12 consecutive months and were evaluated for safety and tolerability, Treg function, serum biomarkers of oxidative stress and inflammation, and clinical functioning as measured by the ALSFRS-R scale. The dual-mechanism investigational biologic

combination combines low dose Interleukin-2 that is intended to enhance anti-inflammatory regulatory T cell function with a fusion protein that is intended to suppress pro-inflammatory cell function and has been designed to be administered subcutaneously to minimize treatment burden for patients and caregivers.

ALS is a disease of the parts of the nervous system that control voluntary muscle movement. In ALS, motor neurons (nerve cells that control muscle cells) are gradually lost. As these motor neurons are lost, the muscles they control become weak and then nonfunctional, thus leading to muscle weakness, disability, and eventually death. ALS is the most common form of motor neuron disease.

The study was conducted at the Houston Methodist Research Institute (Houston, Texas) by Stanley Appel, M.D., Jason Thonhoff, M.D., Ph.D., and David Beers, Ph.D.

Dr. Appel is chair of Coya's Scientific Advisory Board and is former chair of the Stanley H. Appel Department of Neurology. He is the director of the Ann Kimball & John W. Johnson Center for Cellular Therapeutics, Professor of Neurology at Weill Cornell Medical College, and the Peggy and Gary Edwards Distinguished Chair for the Treatment and Research of ALS at the Houston Methodist Research Institute.

#### Presentation details are:

- Title: Novel Treg-modulating Immunotherapy Targets Inflammation in ALS.
- Date: Tuesday, March 21, 2023, at 11:00 am CST
- Conference: 2023 MDA Clinical & Scientific Conference (https://www.mdaconference.org)

## About Coya Therapeutics, Inc.

Headquartered in Houston, TX, Coya Therapeutics, Inc. (Nasdaq: COYA) is a clinical-stage biotechnology company developing proprietary treatments focused on the biology and potential therapeutic advantages of regulatory T cells ("Tregs") to target systemic inflammation and neuroinflammation. Dysfunctional Tregs underlie numerous conditions including neurodegenerative, metabolic, and autoimmune diseases, and this cellular dysfunction may lead to a sustained inflammation and oxidative stress resulting in lack of homeostasis of the immune system.

Coya's investigational product candidate pipeline leverages multiple therapeutic modalities aimed at restoring the anti-inflammatory and immunomodulatory functions of Tregs. Coya's therapeutic platforms include Treg-enhancing biologics, Treg-derived exosomes, and autologous Treg cell therapy. Coya's 300 Series product candidates, COYA 301 and COYA 302, are biologic therapies intended to enhance Treg function and expand Treg numbers. COYA 301 is a cytokine biologic for subcutaneous administration intended to enhance Treg function and expand Treg numbers in vivo, and COYA 302 is a biologic combination for subcutaneous and/or intravenous administration intended to enhance Treg function while depleting T effector function and activated macrophages. These two

mechanisms may be additive or synergistic in suppressing inflammation. For more information about Coya, please visit **www.coyatherapeutics.com** 

## About Muscle Dystrophy Association

Muscular Dystrophy Association (MDA) is the #1 voluntary health organization in the United States for people living with muscular dystrophy, ALS, and related neuromuscular diseases. For over 70 years, MDA has led the way in accelerating research, advancing care, and advocating for the support of our families. MDA's mission is to empower the people we serve to live longer, more independent lives. To learn more visit mda.org and follow MDA on Instagram, Facebook, Twitter, TikTok, LinkedIn, and YouTube.

# Forward-Looking Statements

This press release contains "forward-looking" statements that are based on our management's beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our current and future financial performance, business plans and objectives, current and future clinical and preclinical development activities, timing and success of our ongoing and planned clinical trials and related data, the timing of announcements, updates and results of our clinical trials and related data, our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, industry environment and potential market opportunities. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward-looking statements.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but not limited to, those related to risks associated with the impact of COVID-19; the success, cost and timing of our product candidate development activities and ongoing and planned clinical trials; our plans to develop and commercialize targeted therapeutics; the progress of patient enrollment and dosing in our preclinical or clinical trials; the ability of our product candidates to achieve applicable endpoints in the clinical trials; the safety profile of our product candidates; the potential for data from our clinical trials to support a marketing application, as well as the timing of these events; our ability to obtain funding for our operations; development and commercialization of our product candidates; the timing of and our ability to obtain and maintain regulatory approvals; the rate and degree of market acceptance and clinical utility of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our commercialization, marketing and manufacturing capabilities and strategy; future agreements with third parties in connection with the commercialization of our product candidates; our expectations regarding our ability to obtain and maintain intellectual property protection; our dependence on third party manufacturers; the success of competing therapies

or products that are or may become available; our ability to attract and retain key scientific or management personnel; our ability to identify additional product candidates with significant commercial potential consistent with our commercial objectives; ; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. Moreover, we operate in a very competitive and rapidly changing environment, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. We undertake no obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

## **Investor Contact**

David Snyder

david@coyatherapeutics.com

Hayden IR James Carbonara (646)-755-7412

James@haydenir.com

### Media Contact

lessica Starman

media@coyatherapeutics.com

Source: Coya Therapeutics, Inc.